

ANTIFUNGAL- miconazole nitrate cream

Actavis Mid Atlantic LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Miconazole Nitrate Antifungal Cream

Active ingredient

Miconazole nitrate, USP 2%

Purpose

Antifungal

Uses

- Proven clinically effective in the treatment of most athlete's foot, jock itch and ringworm
- for effective relief of itching, scaling, cracking, burning and discomfort

Warnings

For external use only

Do not use

on children under 2 years of age unless directed by a doctor.

When using this product

- avoid contact with the eyes

Stop use and ask a doctor if

- irritation occurs
- there is no improvement within 4 weeks (for athlete's foot and ringworm) or within 2 weeks (for jock itch)

Keep out of reach of children section

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- wash the affected area and dry thoroughly
- apply a thin layer of the product over affected area twice daily (morning and night), or as directed by a doctor
- supervise children in the use of this product
- for athlete's foot: pay special attention to spaces between the toes; wear well-fitting, ventilated shoes, and change shoes and socks at least once daily

- for athlete's foot and ringworm, use daily for 4 weeks; for jock itch, use daily for 2 weeks
- if condition lasts longer, contact a doctor
- this product is not effective on the scalp or nails

Other information

- do not use if seal on tube is punctured or is not visible
- to puncture the seal, reverse the cap and place the puncture-top onto the tube. Push down firmly until seal is open. To close, screw the cap back onto the tube
- store at controlled room temperature 59°-86°F (15°-30°C).
- before using any medication, read all label directions. Keep carton, it contains important information.

Inactive ingredients

benzoic acid, butylated hydroxyanisole, mineral oil, oleoyl polyoxylglycerides, pegoxol 7 stearate, purified water

Questions?

1-800-432-8534 between 9 am and 4 pm EST, Monday- Friday.

Principal Display Panel

Compare to the active ingredient in Micatin® Antifungal Cream
NDC 0472-0735-14

Actavis

Antifungal Cream

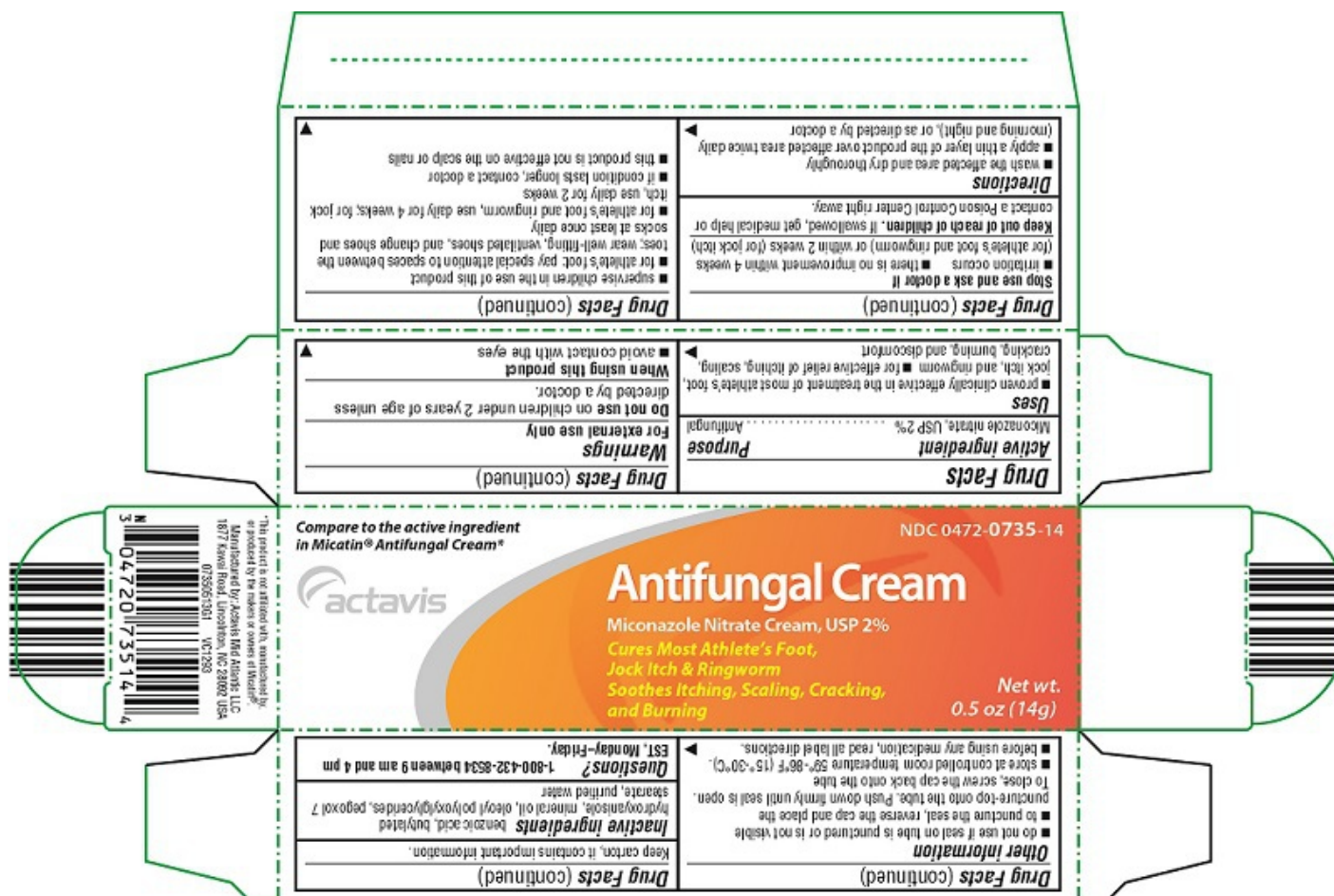
Miconazole Nitrate Cream, USP 2%

Cures Most Athlete's Foot,

Jock Itch & Ringworm

Soothes Itching, Scaling, Cracking, and Burning

Net wt. 0.5 oz (14g)



ANTIFUNGAL

miconazole nitrate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0472-0735
Route of Administration	TOPICAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)	MICONAZOLE NITRATE	20 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
BENZOIC ACID (UNII: 8SKN0B0MIM)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
MINERAL OIL (UNII: T5L8T28FGP)	
PEGOXOL 7 STEARATE (UNII: 3EW5AXE5X5)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0472-0735-14	1 in 1 CARTON		
1		14 g in 1 TUBE		
2	NDC:0472-0735-56	1 in 1 CARTON		
2		28 g in 1 TUBE		
3	NDC:0472-0735-42	1 in 1 CARTON		
3		42.5 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part333C	05/01/2007	

Labeler - Actavis Mid Atlantic LLC (809515898)

Revised: 5/2014

Actavis Mid Atlantic LLC